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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte SIDNEY T. SMITH, STEPHEN LEE SMITH,
JAMES P. DIORIO, SUSAN K. YOUNG,
DAVID V. BACEHOWSKI, and T. MICHAEL DENNEHEY

Appeal 2009-006960
Application 10/634,663
Technology Center 1700

Decided: January 21, 2010

Before BRADLEY R. GARRIS, CHUNG K. PAK, and TERRY J. OWENS,
Administrative Patent Judges.

OWENS, *Administrative Patent Judge.*

DECISION ON APPEAL

STATEMENT OF THE CASE

The Appellants appeal under 35 U.S.C. § 134(a) from the Examiner's rejection of claims 1, 3-11, 19-21 and 23-53, which are all of the pending claims. We have jurisdiction under 35 U.S.C. § 6(b).

The Invention

The Appellants claim a cell culture container. Claim 1 is illustrative:

1. A cell culture container comprising:

a closed supporting container comprising a first flexible exterior side wall connected to a portion of an opposing second flexible exterior side wall along a peripheral seal to define a containment area, the first side wall being constructed from a gas permeable material selected from the group consisting of polymeric material, paper, and fabric, the first side wall having a gas permeability sufficient to permit cellular respiration, and the second side wall being constructed from a material selected from the group consisting of polymeric material, paper, fabric, and foil, wherein at least one of the first and the second side wall comprises an interior surface comprising an ethylene vinyl acetate copolymer; and

a fibrin matrix layer on a portion of the interior surface of the first side wall or the second side wall of the supporting container.

The References

Codner	5,686,304	Nov. 11, 1997
Turner	5,912,177	Jun. 15, 1999
Smith	5,935,847	Aug. 10, 1999
Delmotte	5,989,215	Nov. 23, 1999
Toner	6,759,245 B1	Jul. 6, 2004
		(filed Jun. 21, 2000)

The Rejections

The claims stand rejected under 35 U.S.C. § 103 as follows: claims 1, 3-11, 19-21, 23-34 and 48-53 over Smith in view of Toner or Turner, further in view of Codner, and claims 35-47 over Smith in view of Toner or Turner, further in view of Codner and Delmotte.¹

¹ The statement of the rejection of claims 36-46 on page 10 of the Examiner's Answer followed by the next paragraph addressing claims 35-37 and the last paragraph on page 11 addressing claim 47 indicate that the

OPINION

We affirm the Examiner's rejections.

*Rejection of claims 1, 3-11, 19-21, 23-34 and 48-53 over Smith
in view of Toner or Turner, further in view of Codner*

Issue

Have the Appellants shown reversible error in the Examiner's determination that the applied prior art would have rendered *prima facie* obvious, to one of ordinary skill in the art, a wall interior surface comprising an ethylene vinyl acetate copolymer?

Findings of Fact

Smith discloses, regarding US 4,939,151 (col. 2, ll. 1-12):

The bag disclosed in the '151 Patent is constructed from two side walls. The first side wall is made of ethylene-vinyl acetate ("EVA") which may be positively or negatively charged. The second side wall is constructed from a gas permeable film such as ethylene-vinyl acetate or a polyolefin. The first side wall is sealed to the second side wall along their edges. While EVA can hold an electrostatic charge, the charge has the undesirable tendency to decay over time. Eventually, the decay of the charge on EVA will render the container ineffective for growing adherent cells. Rigid styrene flasks with an electrostatic charge are known, and show less of a tendency to lose charge over time.

Smith's invention is "a multilayer, flexible, gas permeable container having an inner growing surface of polystyrene, which is conducive to the culture of cells" (col. 1, ll. 21-24). The inner growing surface of polystyrene is an ultra-thin polystyrene layer having a thickness of about 0.0001 to about

Examiner inadvertently omitted claims 35 and 47 from the statement of the rejection. We therefore consider claims 35 and 47 to be rejected.

0.0010 inches (col. 2, ll. 24-30, 52-55). That layer can be used in combination with an EVA outer layer (col. 5, ll. 42-45).

Toner discloses a cell culturing device having, between two rigid walls (50), a gas-permeable, liquid-impermeable membrane (30) that comprises a polymer selected from a list including polystyrene, poly(ethyl vinyl acetate), and composites, mixtures or copolymers of the listed polymers (col. 5, ll. 9-14). The membrane's cell culturing surface (41) can be coated with an extracellular matrix which can be fibrin to induce cell adhesion and promote cell function (col. 5, ll. 14-16; col. 11, ll. 42-52).

Turner discloses a system for selectively immobilizing stem cells, for example, those from the haematopoietic progenitor compartment (HPC), which comprises a substrate having a coating comprising a fibrin matrix, together with a substance capable of binding to the fibrin matrix and having a binding site for binding to an RGD amino acid sequence for binding to the stem cells (col. 2, ll. 44-50). “The limited ability of fibronectin or other binding substance to bind to the substrate is substantially enhanced by coating the substrate with a fibrin matrix” (col. 4, ll. 12-14). “Fibrin-fibronectin coatings show good stem cell adhesion” (col. 4, ll. 27-28).

Codner discloses a cell culturing bag made of ethylene vinyl acetate copolymer (col. 6, ll. 51-58).

Analysis

The Appellants argue that Smith's disclosure that “[e]ventually, the decay of the charge on EVA will render the container ineffective for growing adherent cells” (col. 2, ll. 9-10) teaches away from an interior surface comprising ethylene vinyl acetate (Br. 15-16; Reply Br. 3).

That disclosure would have indicated to one of ordinary skill in the art that EVA would be a suitable interior surface material until the charge eventually decays sufficiently that it is no longer effective. Moreover, Toner's disclosure that coating with fibrin a cell culture material which can be ethylene vinyl acetate induces cell adhesion and promotes cell function (col. 5, ll. 8-16; col. 11, ll. 27-52) would have indicated to one of ordinary skill in the art that fibrin-coated ethylene vinyl acetate is a suitable cell growth material.

The Appellants argue that one of ordinary skill in the art would not have combined Smith and Toner because Toner's disclosure of rigid and impermeable exterior walls (50) expressly teaches away from Smith's flexible, gas-permeable container (Br. 14-15).

Toner's cell culture surface is not the rigid impermeable walls (50) but, rather, is the surface (41) of the gas permeable membrane (30) (col. 11, ll. 31-32, 36-41). Toner's disclosure that the gas permeable membrane can be made of polystyrene or ethylene vinyl acetate copolymer and can be coated with an extracellular matrix which can be fibrin to induce cell adhesion and promote cell function (col. 5, ll. 8-16; col. 11, ll. 27-52) would have led one of ordinary skill in the art, through no more than ordinary creativity, to use fibrin-coated ethylene vinyl acetate copolymer as an alternative to Smith's polystyrene. *See KSR Int'l. Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007) (In making an obviousness determination one "can take account of the inferences and creative steps that a person of ordinary skill in the art would employ").²

² The Appellants acknowledge that "Toner teaching [sic: teaches] using fibrin as a coating matter, which is already known in the art" (Br. 15).

The Appellants argue that Toner, at column 9, lines 39-42, discloses EVA only as a middle layer in a three-layered co-extruded film of styrene-butadiene-styrene/ethylene vinyl acetate/styrene-butadiene styrene (Reply Br. 4).

Toner, at column 5, lines 9-15, does not limit the ethylene vinyl acetate to a middle layer but, rather, discloses that the gas-permeable, liquid-impermeable membrane can be ethylene vinyl acetate.

The Appellants argue that Toner's disclosure (col. 2, ll. 35-50) of an open or flow-through cell culturing device teaches away from the Appellants' closed container (Br. 16).

That argument is not persuasive because it is not supported by evidence or technical reasoning which shows that one of ordinary skill in the art would have considered Toner's cell culturing materials to be effective in a flow-through system but not in a closed system.

The Appellants argue that Turner fails to disclose or suggest an ethylene vinyl acetate copolymer and Codner fails to disclose or suggest the use of fibrin for growing cells (Br. 16).

Codner would have indicated to one of ordinary skill in the art that ethylene vinyl acetate copolymer is a suitable cell growth material (col. 6, ll. 51-57), and Turner would have indicated to one of ordinary skill in the art that a fibrin matrix is suitable for enhancing the binding ability of a binding substance such as fibronectin to a substrate and to stem cells (col. 3, ll. 47-54; col. 4, ll. 12-14, 26-27). Hence, Codner and Turner would have led one of ordinary skill in the art, through no more than ordinary creativity, to use fibrin-coated ethylene vinyl acetate as an alternative to Smith's polystyrene. *See KSR*, 550 U.S. at 418.

The Appellants argue that because adherent cells can grow only on the surface of polystyrene, whereas a fibrin matrix provides a three-dimensional framework for the culture of cells, a skilled artisan would understand that a polystyrene layer and a fibrin matrix operate in different manners and are not functionally equivalent (Reply Br. 3-4).

Even if that difference in the surface structures of polystyrene and a fibrin matrix exists, the above-discussed reference disclosures would have indicated to one of ordinary skill in the art that both polystyrene and fibrin-coated ethylene vinyl acetate provide suitable surfaces for growing cells.

Conclusion of Law

The Appellants have not shown reversible error in the Examiner's determination that the applied prior art would have rendered *prima facie* obvious, to one of ordinary skill in the art, a wall interior surface comprising an ethylene vinyl acetate copolymer.

*Rejection of claims 35-47 over Smith in view of Toner
or Turner, further in view of Codner and Delmotte*

Issue

Have the Appellants shown reversible error in the Examiner's determination that one of ordinary skill in the art would have combined the disclosures of Smith and Delmotte?

Findings of Fact

Delmotte discloses "a medical fluid delivery system for volumetrically delivering fibrinogen and thrombin to form fibrin on a surface" (col. 1, ll. 15-17).

Analysis

The Appellants argue that “*Delmotte* teaches away from a closed support container having flexible and gas permeable exterior sidewalls in accordance with the present claims” (Br. 18; Reply Br. 6).

The Examiner relies upon Smith, not *Delmotte*, for a disclosure of a closed support container having flexible and gas permeable exterior sidewalls (Ans. 12). The Examiner relies upon *Delmotte* for a disclosure of fibrin made by mixing a solution of fibrinogen and factor XIII with a solution of thrombin and calcium (Ans. 16-17). The Appellants acknowledge that fibrin made by that method was known in the art (Spec. 14-22). The Appellants have not established that the fibrin in their claimed cell culture container differs from that of *Delmotte*, Toner or Turner, or that one of ordinary skill in the art would have considered the fibrin of *Delmotte*, Toner or Turner to be ineffective in Smith’s closed container.

Conclusion of Law

The Appellants have not shown reversible error in the Examiner’s determination that one of ordinary skill in the art would have combined the disclosures of Smith and *Delmotte*.

DECISION/ORDER

The rejections under 35 U.S.C. § 103 of claims 1, 3-11, 19-21, 23-34 and 48-53 over Smith in view of Toner or Turner, further in view of Codner, and claims 35-47 over Smith in view of Toner or Turner, further in view of Codner and *Delmotte* are affirmed.

It is ordered that the Examiner’s decision is affirmed.

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No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

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